S. 877

To amend section 353 of the Public Health Service Act to exempt physician office laboratories from the clinical laboratories requirements of that section.

IN THE SENATE OF THE UNITED STATES

MAY 26 (legislative day, MAY 15), 1995

Mrs. Hutchison introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

A BILL

To amend section 353 of the Public Health Service Act to exempt physician office laboratories from the clinical laboratories requirements of that section.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 **SECTION 1. SHORT TITLE.**
- 4 This Act may be cited as the "Clinical Laboratory
- 5 Improvement Act Amendments of 1995".
- 6 SEC. 2. EXEMPTION OF PHYSICIAN OFFICE LABORATORIES.
- 7 Section 353(d) of the Public Health Service Act (42
- 8 U.S.C. 263a(d)) is amended—
- 9 (1) by redesignating paragraphs (2), (3), and
- 10 (4) as paragraphs (3), (4), and (5), respectively;

1	(2) by inserting after paragraph (1) the follow-
2	ing new paragraph:
3	"(2) Exemption of physician office lab-
4	ORATORIES.—
5	"(A) In general.—Except as provided in
6	subparagraph (B), a clinical laboratory in a
7	physician's office (including an office of a group
8	of physicians) which is directed by a physician
9	and in which examinations and procedures are
10	either performed by a physician or by individ-
11	uals supervised by a physician solely as an ad-
12	junct to other services provided by the physi-
13	cian's office is exempt from this section.
14	"(B) Exception.—A clinical laboratory
15	described in subparagraph (A) is not exempt
16	from this section when it performs a pap smear
17	(Papanicolaous Smear) analysis.
18	"(C) Definition.—For purposes of sub-
19	paragraph (A), the term 'physician' has the
20	same meaning as is prescribed for such term by
21	section 1861(r) of the Social Security Act (42
22	U.S.C. 1395x(r)).";
23	(3) in subparagraph (A) and (B) of paragraph
24	(3) (as so redesignated) by striking "paragraph (3)"

each place that such appears and inserting "paragraph (4)"; and

(4) in paragraphs (4) and (5) (as so redesignated), by striking "paragraph (2)" each place that such appears and inserting "paragraph (3)".

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